

ANTI-FUNGAL BUTTERY BALM LADY BITS- miconazole nitrate 2% ointment

Derma Care Research Labs, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Miconazole Nitrate 2%

Antifungal

Cures most tinea cruris "jock itch" and tinea corporis "ring worm". Soothes itching, burning, cracking.

For external use only.

Avoid contact with eyes. **Do not use** on children under 2 years of age unless directed by a doctor.

Keep out of reach of children.

Clean the affected area thoroughly. Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor. If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor.

aloe barbadensis leaf extract, althaea officinalis root extract, beeswax, butyrospermum parkii (shea) butter, calendula officinalis flower extract, cocos nucifera (coconut) oil, cucumis melo (melon) fruit extract, dipteryx odorata seed extract, glycerin, hydrogenated vegetable oil, olea europaea (olive) fruit oil, pimpinella anisum (anise) fruit extract, ricinus communis (castor) seed oil, theobroma cacao (cocoa) extract, triethyl citrate, vanilla planifolia fruit extract, water



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miconazole nitrate 2% ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-133
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
COCOA (UNII: D9108TZ9KG)	
VANILLA (UNII: Q74T35078H)	
WATER (UNII: 059QF0KO0R)	
MELON (UNII: 5CIT1X6U5V)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
DIPTERYX ODORATA SEED (UNII: D43A5L1U6L)	
GLYCERIN (UNII: PDC6A3C0OX)	
CORN OIL (UNII: 8470G57WFM)	
RICINUS COMMUNIS SEED (UNII: 7EK4SFN1TX)	
SHEA BUTTER (UNII: K49155WL9Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
ANISE (UNII: 21C2F5E8RE)	
COCOA BUTTER (UNII: 512OYT1CRR)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-133-01	25 g in 1 JAR; Type 0: Not a Combination Product	05/03/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/03/2019	

Labeler - Derma Care Research Labs, LLC (116817470)

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Derma Care Research Labs, LLC